Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1   1.   (Currently amended): A computer-implemented method for managing
2   stability studies, the method comprising:
3   storing, in a central database communicatively coupled to a data processing
4   system, information that defines requirements needed or actions to perform for each stage in a
5   plurality of stages associated with at least one stability study;
6   selecting, with one or more processors associated with the data processing system,
7   a stage to process from the plurality of stages;
8   determining, with one or more processors associated with the data processing
9   system, one or more requirements needed for the stage of the at least one stability study based on
10   information retrieved from the central database for the selected stage;
11   automatically generating, with the one or more processors associated with the data
12   processing system, a first graphical user interface based on the one or more determined
13   requirements needed for the stage, the first graphical user interface configured to display the one
14   or more determined requirements needed for the stage and accept input from users of the first
15   graphical user interface for the determined one or more requirements needed for the stage;
16   ~~forwarding, to a first client computer,~~ outputting, from the data processing
17   system, information configured to display [[a]] the first graphical user interface on a display
18   device ~~in a first set of one or more graphical user interfaces that enables users of the first client~~
19   ~~computer to create stability studies by specifying requirements that need to be fulfilled for the~~
20   ~~stability studies;~~
21   ~~receiving, at a first host computer, first input specified by a user of the first client~~
22   ~~computer via the first interface in the first set of one or more graphical user interfaces, the first~~
23   ~~input indicative of a set of requirements for at least one stability study;~~

24   determining, with one or more processors associated with the data processing

25   system, whether one or more actions are to be performed for the stage of the at least one stability

26   study based on the information retrieved from the central database for the selected stage;

27   automatically generating, with the one or more processors associated with the data

28   processing system, a second graphical user interface based on one or more determined actions to

29   be performed for the stage, the second graphical user interface configured to display prompts for

30   the one or more determined actions to be performed and accept input from users of the second

31   graphical user interface for the determined one or more actions to be performed;

32   ~~forwarding, to the first client computer,~~ output, from the data processing system,

33   information configured to display [[a]] the second graphical user interface on a display device ~~in~~

34   ~~the first set of one or more graphical user interfaces that enables the users of the first client~~

35   ~~computer to create workflows associated with stages of stability studies, a workflow including~~

36   ~~information configured to prompt a workflow participant to perform one or more actions that~~

37   ~~need to be taken during a stage associated with a stability study in order to fulfill requirements~~

38   ~~specified for the stability study;~~

39   ~~receiving, at the first host computer, input specified by the user of the first client~~

40   ~~computer via the second interface in the first set of one or more graphical user interfaces, the~~

41   ~~second input indicative of a set of workflows associated with a plurality of stages of the at least~~

42   ~~one stability study, each workflow in the set of workflows specifying a set of actions that need to~~

43   ~~be taken during each stage in the plurality of stages of the at least one stability study;~~

44   ~~forwarding, to the first client computer, information configured to display a third~~

45   ~~interface in the first set of one or more graphical user interfaces that enable the users of the first~~

46   ~~client computer to specify business rules for the stability studies;~~

47   ~~receiving, at the first host computer, third input specified by the user via the third~~

48   ~~interface in the first set of one or more graphical user interfaces, the third input indicative of a set~~

49   ~~of business rules for the at least one stability study;~~

50   ~~generating, at a data processing device, a second set of one or more graphical user~~

51   ~~interfaces for the at least one stability study based on the set of requirements that need to be~~

52   ~~fulfilled for the at least one stability study, the set of workflows associated with the plurality of~~

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53 stages of the at least one stability study, and the set of business rules for the at least one stability

54 study, wherein the second set of one or more graphical user interfaces define the set of

55 requirements for the at least one stability study;

56 forwarding, to a second client computer, information configured to display one or

57 more interfaces in the second set of graphical user interfaces;

58 receiving, at the data processing system second host computer, information

59 specified by one or more users of the second client computer via the one or more first or second

60 graphical user interfaces in the second set of interfaces, the received information for fulfilling

61 satisfying at least one of the one or more determined requirements or resulting from performance

62 to the one or more actions of the at least one stability study; and

63 validating, with the one or more processors associated with the data processing

64 system by the second host computer, the received information against [[the]] a set of business

65 rules for the at least one stability study to determine whether the received information is

66 acceptable.

1 2. (Previously presented): The method of claim 1, further comprising if the

2 information specified by the one or more users of the second client computer is acceptable,

3 storing the information specified by the one or more users of the second client computer using a

4 storage device.

1 3. (Previously presented): The method of claim 1, further comprising:

2 determining, by the data processing device, whether the set of requirements for

3 the at least one stability study have been completed; and

4 if the set of requirements have not been completed, requesting, using the data

5 processing device, additional information for the requirements in the set of requirements that

6 have not been completed.

1 4. (Previously presented): The method of claim 1, further comprising:

2 determining, by the data processing device, whether approval from a user is

3 needed for the information specified by the one or more users of the second client computer

4   based on the set of workflows associated with the plurality of stages of the at least one stability

5   study.

1   5.   (Previously presented): The method of claim 4, further comprising:

2   receiving, at the data processing device, an indication of approval for the

3   information specified by the one or more users of the second client computer; and

4   storing the indication using a storage device.

1   6.   (Original): The method of claim 5, wherein the indication comprises at

2   least one of an electronic signature and captured signature.

1   7.   (Previously presented): The method of claim 4, further comprising:

2   receiving, at the data processing device, an indication of disapproval for the

3   information specified by the one or more users of the second client computer;

4   determining, by the data processing device, requirements that need to be

5   completed for approval; and

6   requesting, using the data processing device, that the determined requirements be

7   completed for approval.

1   8.   (Previously presented): The method of claim 1, wherein the first set of

2   one or more graphical user interfaces include an interface for a stage in the plurality of stages in

3   the at least one stability study.

1   9.   (Original): The method of claim 8, wherein the plurality of stages

2   comprise at least two of a stability study setup criteria, stability study planning criteria, initial

3   sampling and testing criteria, stability study launch criteria, stability study testing criteria, and

4   stability study evaluation criteria.

1   10.   (Currently amended): The method of claim 1, further comprising

2   outputting, from the data processing device, information summarizing the at least one stability

3   study.

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1   11.   (Previously presented): The method of claim 1, further comprising
2 determining, by the data processing device, a result of the at least one stability study.

1   12.   (Previously presented): The method of claim 11, wherein determining, by
2 the data processing device, the result of the at least one stability study comprises receiving the
3 result from a user.

          13-26 (Canceled).

1   27.   (Previously presented): A tangible computer readable medium storing a
2 set of instructions for managing a stability study when executed by a processor of a data
3 processing system, the computer readable medium comprising:
4   code for forwarding information configured to display a first interface in a first set
5 of one or more graphical user interfaces that enable a user to create stability studies by specifying
6 requirements that need to be fulfilled for the stability studies;
7   code for receiving first input via the first interface in the first set of one or more
8 graphical user interfaces, the first input indicative of a set of requirements for at least one
9 stability study;
10   code for forwarding information configured to display a second interface in the
11 first set of one or more graphical user interfaces that enable a user to create workflows associated
12 with stages of stability studies, a workflow including information configure to prompt a
13 workflow participant to perform one or more actions that need to be taken during a stage
14 associated with a stability study in order to fulfill requirements specified for the stability study;
15   code for receiving second input via the second interface in the first set of one or
16 more graphical user interfaces, the second input indicative of a set of workflows associated with
17 a plurality of stages of the at least one stability study, each workflow in the set of workflows
18 specifying a set of actions that need to be taken during for each stage in the plurality of stages of
19 the at least one stability study;

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20 code for forwarding information configured to display a third interface in the first
21 set of one or more graphical user interfaces that enable a user to specify a set of business rules
22 for stability studies;
23 code for receiving third input via the third interface in the first set of one or more
24 graphical user interfaces, the third input indicative of a set of business rules for the at least one
25 stability study;
26 code for generating a second set of one or more graphical user interfaces for the at
27 least one stability study based on the set of requirements that need to be fulfilled for the at least
28 one stability study, the set of workflows associated with the plurality of stages of the at least one
29 stability study, and the set of business rules for the at least one stability study, wherein the
30 second set of one or more fourth interfaces define the set of requirements for the at least one
31 stability study;
32 code for forwarding information configured to display one or more interfaces in
33 the second set of graphical user interfaces;
34 code for receiving fourth input via the one or more interfaces in the second set of
35 graphical user interfaces, the received fourth input for fulfilling the requirements of the at least
36 one stability study; and
37 code for validating the received fourth input against the set of business rules for
38 the at least one stability study to determine whether the fourth input is acceptable.

1 28. (Previously presented): The computer readable medium of claim 27,
2 further comprising code for storing the fourth input when the fourth input is acceptable.

1 29. (Previously presented): The computer readable medium of claim 27,
2 further comprising:
3 code for determining whether the set of requirements for the at least one stability
4 study have been completed; and
5 code for requesting additional information for the requirements in the set of
6 requirements that have not been completed.

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30. (Previously presented): The computer readable medium of claim 27, further comprising:

code for determining whether approval from a user is needed for the fourth input based on the set of workflows associated with the plurality of stages of the at least one stability study.

31. (Previously presented): The computer readable medium of claim 30, further comprising:

code for receiving an indication of approval for the fourth input; and

code for storing the indication.

32. (Previously presented): The computer readable medium of claim 31, wherein the indication comprises at least one of an electronic signature and captured signature.

33. (Previously presented): The computer readable medium of claim 30, further comprising:

code for receiving an indication of disapproval for the fourth input;

code for determining requirements that need to be completed for approval; and

code for requesting that the determined requirements be completed for approval.

34. (Previously presented): A system for managing stability studies, the system comprising:

a set of one or more processors; and

one or more memories coupled to the set of processor, the one or more memories including:

a first set of one or more graphical user interfaces configured to enable a user to create stability studies by specifying requirements that need to be fulfilled for stability studies, workflows associated with stages of stability studies, and business rules for stability studies;

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10   a database configured to store information associated with the

11   requirements, the workflows, and the business rules for stability studies, wherein a workflow

12   includes information configured to prompt a user to perform one or more actions that need to be

13   taken during a stage associated with a stability study in order to fulfill requirements specified for

14   the stability study;

15   a stage selector configured to select a stage of a stability study;

16   a stage information manager configured to receive from the database one

17   or more requirements that need to be fulfilled for the selected stage and one or more workflows

18   associated with the selected stage, to generate a second set of one or more graphical user

19   interfaces that defines the one or more requirements for the selected stage that need to be

20   fulfilled and actions associated with the selected stage that need to be performed;

21   a stage information processor configured to receive input specified via the

22   second set of graphical user interfaces and to validate the input against business rules associated

23   with the selected stage to determine whether the input is acceptable.

1   35.   (Previously presented): The system of claim 34 wherein the first set of

2   one or more graphical user interfaces is further configured to enable the user to create a

3   specification for a first stability study as an overlay using a specification for a second stability

4   study as a base.